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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,025	12/27/2006	Kunihide Shikata	81880.0145	5434
26021	7590	01/14/2010	EXAMINER	
HOGAN & HARTSON L.L.P. 1999 AVENUE OF THE STARS SUITE 1400 LOS ANGELES, CA 90067				WIESE, NOAH S
ART UNIT		PAPER NUMBER		
1793				
			NOTIFICATION DATE	DELIVERY MODE
			01/14/2010	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/578,025	SHIKATA ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	NOAH S. WIESE	1793

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 27 April 2006.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 21-40 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 21-40 is/are rejected.  
 7) Claim(s) 39 and 40 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 27 April 2006 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

### ***Status of Application***

1. The claims 21-40 are pending and presented for the examination.

### ***Priority***

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been received by the International Bureau.

### ***Information Disclosure Statement (IDS)***

3. The information disclosure statements (IDS) were submitted on 04/27/2006, 02/19/2008, and 11/04/2009. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner. Please refer to applicant's copy of the 1449 herewith.

### ***Specification***

4. The disclosure is objected to because of the following informalities: the term "atomic rate Titanium/Magnesium of titanium oxide and magnesium oxide" is not clear. It is possible that the term should read "atomic **ratio**". Appropriate correction is required.

### ***Claim Objections***

5. Claim 39-40 are objected to because of the following informalities: the method claims depend from claim 28, which is a product claim. The claims should properly depend from the method claim 38. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 21-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 21 and 38 recite the limitation "contains a metal phase such as molybdenum, tungsten or a mixture of molybdenum and tungsten or metal oxide phase such as strontium oxide or yttrium oxide". This limitation is indefinite because it is not clear if the metal or metal oxide contained is necessarily one from the lists following, or simply one that is similar to those given. A clearer wording would recite that the metal phase or metal oxide is one "selected from the group consisting of..." followed by the specific metals and oxides given in the claims. The claims have been interpreted thusly for examination on merits.

Claim 28 is indefinite because the term "atomic rate Titanium/Magnesium of titanium oxide and magnesium oxide" is not clear. It is possible that the term should read "atomic **ratio**".

Claims 22-37 and 39-40 are rejected under 35 U.S.C. 112 as being dependent from indefinite claims.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 21 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshida et al (JP 2000-191372-A).

Regarding **claim 21**, Yoshida et al teaches a zirconia sintered body for medical use, said zirconia body comprising yttria and alumina in addition to zirconia (see Abstract). Yoshida further teaches that the sintered medical body comprising  $\text{SiO}_2$  and  $\text{TiO}_2$ ; these oxides function as sintering additives. Yoshida teaches that the average grain size of the ceramic is 0.5  $\mu\text{m}$  (see claim 4). Thus, Yoshida teaches a biomedical member meeting all of the limitations of instant claim 21, and the claim is anticipated by the prior art.

Regarding **claim 24**, Yoshida teaches that the sintered body preferably contains 0.1-0.9 wt%  $\text{Al}_2\text{O}_3$ .

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al (US 5525560) in view of Yoshida et al (JP 2000-191372-A).

Regarding **claims 21-22**, Yamazaki et al teaches a zirconia-based ceramic composite material comprising zirconia and 1.5-4.5 mol% yttria along with an additional ceramic phase that can be alumina (see claim 5 and Table 16). Yamazaki also teaches that the ceramic composite comprises a metal selected from Mo, V, and W (see Table 16 and claim 1) in an amount of 0.5-50 vol% (see claim 3); further, average grain size of the metal phase is taught to be 2  $\mu$ m or less (see claim 10), with several examples taught of grain sizes under 1  $\mu$ m (see for instance examples 3-10). Per MPEP 2144.05, in the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists. Yamazaki further teaches that the average grain size of the zirconia phase is less than 1.5  $\mu$ m, with several examples taught prepared from a zirconia powder having an average diameter of 0.3  $\mu$ m. This indicates that an overlapping grain size range is taught, and that average grain size meeting the claimed range is suggested by Yamazaki. Yamazaki teaches that metal grains with sizes of less than 0.1  $\mu$ m are dispersed within the zirconia grains, while metal grains having a size of 0.8  $\mu$ m exist at the grain boundaries of the zirconia grains (see column 17, lines 45-53). Yamazaki does not specify the distribution in metal phase grain sizes, so it is not possible to determine if 95 wt% or more of the phase is located at the grain boundaries. However, because the larger grains are located thusly,

Yamazaki certainly suggests such a distribution. See the above MPEP citation for overlapping ranges.

Claims 21-22 differ from Yamazaki et al because Yamazaki does not teach that the zirconia ceramic composite is used to make a biomedical member. However, it would have been obvious to modify Yamazaki in view of Yoshida et al in order to create such a member from the Yamazaki material because Yoshida teaches that zirconia-alumina ceramics such as those taught by Yamazaki are advantageous in creating biomedical products. One would have had motivation to create biomedical members from the Yamazaki material as taught by Yoshida because doing so would create a potential commercial use for the inventive material. Therefore, claims 21 and 22 are obvious and not patentably distinct over the prior art of record.

Regarding **claim 23**, Yamazaki teaches that the average grain size of the ceramic phase that can be alumina is preferably 0.2  $\mu$ m or less (see column 6, lines 5-7).

Regarding **claim 24**, Yamazaki teaches several examples containing 20 vol%  $\text{Al}_2\text{O}_3$  (see Table 16). This is less than 30 wt%.

13. Claims 21, 32, and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koyama et al (US 5686366) in view of Cales et al (US 2002/0010070).

Regarding **claims 21 and 32**, Koyama et al teaches an alumina-zirconia sintered ceramic comprising an addition alkaline earth oxide phase that can be  $\text{SrO}$  (see column 3, lines 14-20) along with  $\text{SiO}_2$ . The amount of  $\text{SiO}_2$  included in the Koyama ceramic

would function as a sintering additive. Koyama teaches an example comprising 20 wt%  $\text{ZrO}_2$ , 0.23 wt%  $\text{SrO}$ , 0.3 wt%  $\text{SiO}_2$ , and 79.47 wt% (remainder)  $\text{Al}_2\text{O}_3$  (see Table 1). This meets the compositional limitations of instant claim 32. Koyama does not specify the mean grain size of the zirconia phase, but does teach that the starting  $\text{ZrO}_2$  powder has a particle size of 0.1-5  $\mu\text{m}$  (see column 6, lines 8-11). This overlapping size indicates that Koyama suggests a zirconia grain size of 0.5  $\mu\text{m}$  or less.

Claims 21 and 32 differ from Koyama et al because Koyama does not teach that the alumina-zirconia ceramic composite is used to make a biomedical member. However, it would have been obvious to modify Koyama in view of Cales et al in order to create such a member from the Koyama material because Cales teaches that zirconia-alumina ceramics such as those taught by Koyama are advantageous in creating biomedical products. One would have had motivation to create biomedical members from the Koyama material as taught by Cales because doing so would create a potential commercial use for the inventive material. Therefore, claims 21 and 32 are obvious and not patentably distinct over the prior art of record.

Regarding **claim 36**, the claim differs from Koyama in view of Cales as discussed above because Koyama fails to teach that the inventive material has the wear rate property of the claim. However, as also discussed above, Koyama teaches a material that is compositionally and structurally equivalent to that of instant claim 32, and thus it necessarily follows that the material would also have an equivalent specific wear rate. It is well settled that when a claimed composition appears to be substantially the same as a composition disclosed in the prior art, the burden is properly upon the applicant to

prove by way of tangible evidence that the prior art composition does not necessarily possess characteristics attributed to the CLAIMED composition. *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Circ. 1990); *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980); *In re Swinehart*, 439 F.2d 2109, 169 USPQ 226 (CCPA 1971).

Regarding **claim 37**, Cales teaches that materials such as those taught by Koyama et al are used in hip joint prosthesis heads or acetabular cup surfaces (see paragraph 0021).

### ***Double Patenting***

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 21, 25-34, and 36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 7,148,167 ('167). Although the conflicting claims are not identical, they are

not patentably distinct from each other because the claims of '167 are drawn to an alumina/zirconia ceramic comprising alumina, zirconia, MgO, SiO<sub>2</sub>, TiO<sub>2</sub>, and SrO in amounts that meet and closely overlap the limitations of instant claims 21, 25-34, and 36. Thus, the claims of '167 meet the compositional limitations of the above instantly claims. Further, the claims of '167 teach that the zirconia phase of the inventive ceramic has a grain size of 0.5 µm or smaller, that the alumina phase has a grain size of 3 µm or smaller, and that the amount of tetragonal zirconia overlaps the range of instant claims. The claims of '167 also teach that the atomic rate of Titanium/Magnesium meets the limitation of the instant claims, and further teach that the MgO and TiO<sub>2</sub> are partially dissolved in the alumina phase. The property limitations of instant claims 31 and 36 are not specified in the '167 claims, but it necessarily follows that the material taught by the '167 claims would have equivalent properties to the instantly claimed material given the equivalent structure and composition.

The claims of '167 are drawn to a ceramic material and not specifically to a biomedical member; however, the claims still render the instant claims obvious because the preamble limitation "biomedical member" does not give a specific structure or form to the claimed material. Essentially any shape or piece of the ceramic of the '167 claims could be consider a "biomedical member" in that it could be used in the body. Thus, the '167 claims read on the instant claims, and the double patenting rejection of instant claims 21, 25-34, and 36 is proper.

### ***Conclusion***

16. All of the pending claims are rejected.

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noah S. Wiese whose telephone number is 571-270-3596. The examiner can normally be reached on Monday-Friday, 7:30am-5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry Lorengo can be reached on 571-272-1233. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Noah Wiese  
7 January 2010  
AU 1793

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Primary Examiner, Art Unit 1793